

11-30-2012 Notice

Change in Select Agent Regulation

Since 1996 select biological agents and toxins have been regulated by the Federal government. The list of regulated agents has changed modestly over the years. Historically use/possession of toxins on the lists has been excluded from the regulation when de minimus quantities were not exceeded. Click [here](#) to see toxin list and conditions of exclusion.

Effective December 4, 2012, [additional actions \(toxin due diligence\)](#) will be required of principal investigators, physicians, veterinarians, commercial manufacturers, distributors and all who may currently possess or use these toxins in excluded amounts.

The Federal Select Agent Program developed this provision to address the concern that someone might stockpile toxins by receiving multiple orders below the excluded amount. The "toxin due diligence" provision requires that a person transferring toxins in amounts which would otherwise be excluded from the regulation must: (1) use due diligence to assure that the recipient has a legitimate need to handle or use such toxins; and (2) report to the Federal Select Agent Program if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin.

What this means for UAB PIs who currently possess, use, and/or order these toxins:

- 1) the supplier may require documented confirmation that the material they are sending you is being used for a legitimate purpose;
- 2) if you share any amount of the toxin with a colleague (anyone) at UAB or outside of UAB, you will be required to document that the material is being used for a legitimate purpose prior to each transfer and document the transfer in your inventory records for that toxin.

OH&S Select Agent Program would like to help you meet each of these requirements. We can:

- 1) provide suppliers with confirmation that you are proposing or currently engaged in funded research involving the use of the toxin,
- 2) maintain documented confirmation that a transfer to a UAB colleague will meet the transfer requirements of this regulation,
- 3) maintain documented confirmation that a transfer to a colleague outside of UAB will meet the transfer requirements of this regulation,
- 4) respond to inquiries from Federal agencies regarding your exclusion status, and
- 5) report any events that violate Federal regulation.

In order to take advantage of this service, you must:

- 1) Register the project with OH&S Research Safety. If you have not registered, you may do so by completing the form located at: <http://www.healthsafe.uab.edu/pages/biosafety/projectregistration.html> . If you are unsure of the registration status of the project, contact Donna Williamson at dsw@uab.edu or 4-4752. Please do not duplicate registration. This only creates more work for everyone.
- 2) If you currently use or plan to order and use an excluded quantity of toxin on the select agent list, and have not requested an exclusion from the regulation [click here and complete the exemption request form](#). If you are unsure of your exemption status, contact Elaine Broussard at eeb@uab.edu .
- 3) Maintain an up-to-date inventory of toxin receipt/use/transfer/disposal that is available for regulatory review upon request.

Direct questions or program suggestions to Elaine Broussard at eeb@uab.edu